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IN THE

Supreme Court of the United States

APOTEX USA, INC.,

Petitioner,

v.

MERCK PHARMACEUTICAL CO.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Merck has made VASOTEC® since 1983 using a chemical reaction that it kept secret. Merck asserted that Apotex's generic drug (with the same active ingredient that Merck claimed was in its drug) infringed a Canadian patent. Apotex argued that Merck's patent was invalid because it did not disclose the chemical reaction that Merck was keeping secret. Merck ***denied*** that the chemical reaction occurred and ***prevailed*** on that theory in the Canadian suit. During that suit, Apotex discovered a previously undisclosed process to get that chemical reaction. Apotex patented its new process in the United States then sued Merck for infringement. Merck, however, then asserted that it ***did*** make its product using that chemical reaction (which it had ***denied*** before), and that it had used Apotex's process since 1983. Merck moved for summary judgment of invalidity — relying on materials from the Canadian suit as clear and convincing evidence to negate its suppression and concealment, even though Merck had convinced that Canadian court that no reaction occurred. Merck received summary judgment despite its inconsistent and hypocritical positions, amounting to a fraud on the courts and patent system that may well amount to billions of dollars. The Federal Circuit's affirmance is a radical departure from the usual course of judicial proceedings. The district court nullified Apotex's federal property right in its U.S. patent, without trial, despite evidence of Merck's suppression and concealment including expert testimony, documents Merck submitted to the FDA, and Merck's own prior conduct.

The question presented, therefore, is:

Whether summary judgment extinguishing a patentee's federal property right is properly granted in favor of a party

that bears the burden of proving by clear and convincing evidence that it did not suppress or conceal an invention under 35 U.S.C. §§ 102(g), 282, based on disclosures in a foreign court allegedly negating suppression and concealment, when:

(1) its initial secrecy created a presumption that it suppressed and concealed the invention;

(2) it ***never*** disclosed the invention in the United States, but instead the only disclosures allegedly negating suppression and concealment were outside the United States;

(3) it argued in a foreign court that it did not use the invention and ***prevailed*** in that argument when all of the disclosures allegedly negating suppression and concealment were before that foreign court;

(4) its own paid expert testified in that foreign court that those disclosures did ***not*** show use of the invention;

(5) it never identified the alleged prior inventor as required by statute, and

(6) it offered ***no*** evidence that its alleged disclosures outside the U.S. were sufficient for the public in the United States to gain knowledge of the invention to insure its preservation in the public domain; and

(7) an internal document establishes its motive to suppress and conceal the invention by admitting that if the truth got out it might affect worldwide registration and existing approved labelling.

CORPORATE DISCLOSURE STATEMENT

The petitioner Apotex USA, Inc., has no parent corporations and no publicly held company owns more than 10% of its stock.

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Apotex USA, Inc., ("Apotex") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A, 1a-17a) is reported at 254 F.3d 1031 (Fed. Cir. 2001). The opinions of the trial court on summary judgment (Pet. App. B, 18a-38a), and denying reconsideration (Pet. App. C, 39a-45a), are unreported.

STATEMENT OF JURISDICTION

The Federal Circuit entered the judgment of which Apotex seeks review on June 8, 2001. (Pet. App. A at 1a.) It denied rehearing on August 2, 2001. (Pet. App. D at 46a-47a.) Apotex invokes the jurisdiction of this court under 28 U.S.C. § 1254(1) (1994).

CONSTITUTIONAL AND STATUTORY PROVISIONS AT ISSUE

The Constitution gives Congress the power:

> To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries

U.S. Const., art. I, § 8, cl. 8.

The Bill of Rights provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of the common law.

U.S. Const. amend. VII:

The United States Code in Title 35 — Patents, Chapter 100 — Patentability of Inventions, provides that a person is entitled to a patent unless:

> (g)(2) before such person's invention thereof, the invention was made in this country by another inventor ***who had not abandoned, suppressed, or concealed it.***

35 U.S.C. § 102(g) (1994 Supp. V) (emphasis added).

The United States Code in Title 35 — Patents, Chapter 29 — Remedies for the Infringement of Patent, and Other Actions, provides:

> In actions involving the validity or infringement of a patent ***the party asserting invalidity or noninfringement shall give notice*** in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as

> anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and ***the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit.*** In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires.

35 U.S.C. § 282 (1994 Supp. V) (emphasis added).

STATEMENT OF THE CASE

Since the 1980's, Merck has made a hypertension drug under the brand name VASOTEC®. (Pet. App. at 3a.) Merck's labels state that the tablets contain enalapril maleate as its active ingredient. Merck owned a patent claiming enalapril maleate and some other enalapril compounds and uses. Merck's patent stated that a drug containing enalapril maleate could be made by using commonly known adjuvants (L22), which are pharmacological agents added to a drug to increase or aid its effect.

Enalapril maleate is made with maleic acid and is itself slightly acidic. (*See* L2, L22.) It can react with a base such as sodium bicarbonate, which reaction converts the enalapril ***maleate*** to enalapril ***sodium*** and other byproducts. (L2.) The acid and base do not react when mixed in their dry form. Another, older patent taught that the acid enalapril maleate and base sodium bicarbonate would react to yield enalapril sodium (and other products), if mixed with enough water to

make a clear solution. (L2.) A process that requires making a clear solution, however, is undesirable for manufacturing. (L2.)

In the 1980s, a Canadian company, Apotex, Inc. (an affiliate of the petitioner Apotex USA Inc.), tried to make a generic equivalent of VASOTEC®. *Merck & Co., Inc. v. Apotex, Inc.*, 59 C.P.R. (3d) 133 (1994), *reprinted at* L10-L63. Enalapril maleate, however, proved unacceptably unstable, even when combined with common adjuvants. (L2, L58, L91.) Tests by Apotex, Inc., suggested that VASOTEC® might include a sodium compound. (L91.) Apotex, Inc., tried mixing enalapril maleate with sodium bicarbonate (in dry form ***without*** producing an acid-base reaction), but found that the result was even ***less*** stable than enalapril maleate by itself. (L92.) Apotex, Inc., avoided the acid-base reaction because VASOTEC®'s labeling and other sources listed its active ingredient as enalapril ***maleate***, not enalapril ***sodium***. In early 1991, Apotex, Inc., developed an acceptable generic drug that did have enalapril maleate (***not*** enalapril sodium) as its active ingredient, but only after the most difficult product development in its experience. (L58.)

After Merck's Canadian patent on enalapril maleate issued, Merck sued Apotex, Inc., for patent infringement. (L10-L63.) In that litigation, Apotex, Inc., tried to prove Merck's patent invalid.[1] Apotex, Inc., argued that (contrary to statements in Merck's Canadian patent, and unlike the

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1. That suit also included issues of Canadian law not relevant here, such as whether Apotex, Inc., could use product it purchased in Canada before Merck's patent issued.

pharmaceutical Apotex sold) Merck did ***not*** make VASOTEC® by combining the active ingredient enalapril maleate with an adjuvant or a "stabalizer." (L58.) Apotex argued that instead a chemical reaction probably occurred that might itself be inventive, but which was not disclosed in Merck's patent as required by Canadian patent law. (L58.)

Documents Merck produced during the Canadian litigation indicated that VASOTEC® contained sodium bicarbonate or sodium carbonate. From 1983 (when Merck first began making VASOTEC®) until 1988, Merck did not disclose but instead concealed the fact that sodium bicarbonate had anything to do with VASOTEC®. (Pet. App. at 13a-14a.)

Even when Merck eventually disclosed that VASOTEC® included sodium bicarbonate, its disclosures did not negate its earlier suppression and concealment because they were misleading about ***how*** sodium bicarbonate was involved. Those disclosures suggested that sodium bicarbonate was among the final contents of VASOTEC®, ***not*** that it was a starting ingredient used in a chemical reaction to yield a ***different*** product having an active ingredient of enalapril ***sodium*** instead of enalapril ***maleate***. Merck's alleged disclosures included a 1988 French-language publication *Dictionnairre Vidal*, a 1992 Canadian product monograph, and a silent video and narration presented only in the Canadian courtroom where Merck was suing Apotex, Inc. ***None of those disclosures showed an acid-base chemical reaction.*** In the Canadian litigation, Merck even ***denied*** that any reaction occurred.

When Dr. Sherman (the president of Apotex and the chairman of Apotex, Inc.) learned that Merck did include sodium bicarbonate in VASOTEC®, he already knew from the previous experiments at Apotex, Inc., that if the sodium bicarbonate were mixed with the enalapril maleate but the two did not react, then the resulting pharmaceutical would not be stable. (L93-L94.) He therefore thought that an acid-based reaction might be occurring. Dr. Sherman then authorized experiments during the Canadian litigation on reacting enalapril maleate with sodium bicarbonate.

During those experiments, Dr. Sherman discovered that one could react sodium bicarbonate and enalapril maleate in a wet mass, ***without forming a clear solution***. The absence of a clear solution distinguished this process from the prior art. The exact amount of water was critical. Too little water would not produce the desired chemical reaction. Too much water would make a clear solution, as shown in the prior art.

Merck, however, denied that any reaction occurred. It concealed the fact that the reaction occurred even from its own expert in the Canadian litigation, Dr. Schwartz. Dr. Schwartz was the ***only*** U.S. citizen shown to have any knowledge of the Canadian litigation. (*See* Pet. App. at 45a n.1.) The information then available to Dr. Schwartz included the 1988 *Dictionnairre Vidal*, the 1992 Canadian product monograph, the mock-up video and narration by Brian McLeod (an officer of Merck), and a declaration filed by Dr. Sherman. He testified as an expert on pharmaceuticals that ***he could not tell from that information that any reaction occurred.*** Merck ***prevailed*** in its position in that litigation, and the Canadian court concluded that one could not tell that any such reaction was really occurring. (L58.)

Dr. Sherman filed a patent application in the United States that resulted in U.S. Patent Nos. 5,573,780 (issued Nov. 12, 1996) ("the '780 patent") (L1-L5) and 5,690,962 (issued Nov. 25, 1997) ("the '962 patent") (L6-L9). At the time Dr. Sherman filed those applications, Merck had ***denied*** that it used the process he claimed and the Canadian court had ***agreed*** with Merck. Believing that Merck might have used Dr. Sherman's process after the Canadian litigation, Apotex commenced the instant civil action for patent infringement against Merck. Jurisdiction was proper in the United States District Court under 28 U.S.C. § 1338 (1994 Supp. V).

In this litigation, however, Merck reversed its position 180° from the argument on which it had prevailed in Canada. Now Merck argued that it had really invented Dr. Sherman's process, and had been using it since 1983. In combining this new argument with its previous argument on which it had prevailed, Merck tries to ***suck*** and to ***blow*** at the same time. The Federal Circuit (in the decision for which certiorari is here sought) agreed that Merck's failure to disclose the inclusion of sodium bicarbonate before 1988 was by itself enough "to create a genuine issue of material fact that Merck suppressed and concealed" its alleged prior invention. (Pet. App. at 13a-14a.)

Merck, however, argues (and the courts below agreed) that its disclosures from 1988 through and including the 1994 Canadian litigation negated its earlier suppression and concealment. It argues that those disclosures negated suppression and concealment by revealing its starting ingredients and its process. As will be shown below, however, Apotex submitted expert declarations that explained that in this art one would understand all of Merck's disclosures up

until 1994 as listing not starting ingredients in a chemical reaction, but instead the ***final contents of its drug***.

Merck's argument of prior inventorship invalidating the patent is an affirmative defense in a patent infringement action. It was Merck's burden to prove this affirmative defense, and the standard of proof was clear and convincing evidence. 35 U.S.C. § 282 (1994 Supp. V). Merck was also obliged under the statute to identify the alleged prior inventor by name and address. *Id.* Moreover, Merck was required to prove by clear and convincing evidence that no one suppressed or concealed its alleged prior invention in the United States.

Merck moved for summary judgment on its affirmative defense. (Pet. App. at 18a–38a.) As evidence that it did not suppress or conceal the process Dr. Sherman later invented, Merck pointed to its sales of VASOTEC®, the 1988 *Dictionnairre Vidal*, the 1992 Canadian product monograph, and the 1994 mock-up video and accompanying testimony by Brian McLeod. (Pet. App. at 16a; Pet. App. at 35a.) The issue, therefore, was whether Merck's later disclosures were sufficient to negate its earlier suppression and concealment. Apotex opposed summary judgment with expert declarations showing that Merck's alleged disclosures did ***not*** negate Merck's earlier suppression and concealment, but were instead misleading in their own right and thus only further suppressed and concealed the invention.

Merck relied in part on its prior sales of VASOTEC®. The labels on VASOTEC® list the active ingredient as enalapril maleate. Nothing on the label indicates that the active ingredient is really enalapril sodium. Nothing on the label indicates that enalapril maleate is really an initial

ingredient in a process to produce VASOTEC® tablets. The label does not list water, which would be a necessary ingredient in a reaction to produce enalapril maleate but is not an ingredient of the final contents. Instead, the label lists enalapril maleate as the active ingredient in the final contents and does ***not*** identify enalapril sodium as an ingredient in the final contents.

The first alleged disclosure that sodium bicarbonate had anything to do with VASOTEC® was in 1988 in the French-language publication *Dictionnairre Vidal*, some five years after Merck allegedly began using the process. (Pet. App. at 15a.) Merck listed sodium bicarbonate among the contents of RENITEC, the brand name it used in France for VASOTEC®. However, nothing in that entry for RENITEC suggested that these were not in fact the final contents but were instead the starting ingredients for a chemical reaction. The entry omits water, which would be a necessary ingredient in the reaction but is not among the final contents. The entry lists enalapril maleate as the active ingredient in the final contents, and does ***not*** identify enalapril sodium as an ingredient in the final contents.

Starting in 1992, Merck distributed a product monograph in Canada that listed sodium bicarbonate among the contents of VASOTEC®. (*See* Pet. App. at 16a, 45a.) Like the product label and the entry in the 1988 *Dictionnairre Vidal*, nothing in the monograph identifies enalapril maleate and sodium bicarbonate as starting ingredients for a reaction. Instead, the product monograph lists these compounds in the contents of the final product. The product monograph does not list water, which would be a necessary ingredient in the reaction but is not an ingredient of the final contents. The product monograph lists enalapril maleate as the active ingredient in

the final contents, and does ***not*** identify enalapril sodium as an ingredient in the final contents.

During the Canadian litigation in 1994, Brian McLeod, an officer of Merck, narrated a silent video that purported to depict the manufacture of VASOTEC®. Merck admitted that in its video it did ***not*** use the real ingredients from its process, even though there was no reason to substitute ***fake*** ingredients. Apotex filed expert affidavits explaining that the video and the accompanying narration did not negate Merck's prior suppression and concealment. The silent video concealed the use of sodium bicarbonate. It concealed any chemical reaction between the undisclosed sodium bicarbonate and enalapril maleate. The silent video with McLeod's narration did show that Merck used some water and produced a wet mass, but did ***not*** specify how much water Merck used. Nothing in those disclosures identified sodium bicarbonate or where in the process Merck allegedly used that ingredient. Those disclosures also concealed the fact that one of the products of the chemical reaction was enalapril sodium. (L82-L89.)

Apotex offered evidence that the mock-up video Merck used in the 1994 Canadian trial suppressed and concealed the truth — the chemical reaction to convert enalapril maleate to enalapril sodium without making a clear solution enalapril maleate of enalapril sodium and maleic acid sodium salt in water. McLeod admitted "what you are looking at is in fact not really enalapril or the ingredients. We choose not to use the active ingredients in this particular production. . . ." He admitted that Merck made the decision not to identify the actual ingredients in its process during the narration, even though "there was no reason not to." Merck did not tell the Canadian Court, or even its own testifying expert, Dr. Schwartz, that any such reaction occurred.

Dr. Sherman submitted a declaration establishing that McLeod did not indicate whether or not anything dissolved in the water or what the other ingredients were. (L104.) McLeod testified to the presence of a stabilizer, but made no mention of any ***reaction***. (L104.) McLeod thus indicated that Vasotec contained enalapril maleate plus an unidentified stabilizer. (L104.) That implication was ***untrue***. (L104.) Mr. McLeod admitted that the process required "a specified amount of water," but he never specified the amount of water Merck used. (L104.) Too little water would not produce the desired chemical reaction, and too much water would lead to forming a clear solution as in the prior art. McLeod ***concealed*** that the water being added would produce a chemical reaction, and thus ***suppressed*** the aspect of the process that the Apotex patent identifies as a critical improvement over the prior art.

Dr. Scheindlin's declaration as an expert for Apotex in the instant case, (L86-L89, L105-L107), notes that the video conceals the use of sodium bicarbonate. (L106.) The video conceals any chemical reaction between the undisclosed sodium bicarbonate and enalapril maleate. (L106.) The video conceals that one of the products of the chemical reaction is enalapril sodium. (L106.) Dr. Scheindlin specifically stated in his declaration, "Mr. McLeod's use of the word 'stabalizer' in his 1994 testimony ***is deceptive.*** Sodium bicarbonate does not act as a stabalizer per se, but rather is an important ingredient of a chemical reaction to convert enalapril maleate to enalapril sodium." (L106) (emphasis added).

Dr. Schwartz, Merck's own expert in the Canadian action, admitted that he could not tell from those materials whether a reaction occurred. He knew one would get a reaction with

everything in ***solution***, but that is what was already known in the prior art as disclosed in the patents in suit. Dr. Schwartz also admitted that any reaction would depend on the amount of water involved and the order of the mixture, which the video did not explain. He identified several possible roles for sodium bicarbonate in the formula, so the presence of sodium bicarbonate does not reveal the patented process.

Apotex also argued that 35 U.S.C. § 102(g) requires proof that the prior invention was made in the United States, and known to the United States public and that remote disclosure (particularly in view of the fact that Merck concealed that VASOTEC® tablets contained enalapril sodium, disodium maleate, and monosodium maleate and failed to explain that a reaction occurred to convert enalapril maleate to enalapril sodium (L106)) is insufficient to negate a finding of suppression and concealment. Despite the ***unrebutted*** evidence from Apotex's experts that anyone reading the VASOTEC® product monograph could have only one understanding — that each tablet in the bottle, in the physician's hand, and in the patient's mouth contained the active ingredient enalapril maleate, not enalapril sodium, and inactive ingredients including sodium bicarbonate — the district court held that there was no genuine issues of material fact that Merck did not suppress and conceal its invention.

The district court concluded that Apotex failed to raise a genuine issue of material fact as to Merck's affirmative defense, and that no jury could fail to find that Merck had proven invalidity by clear and convincing evidence. The United States Court of Appeals for the Federal Circuit affirmed, further concluding on summary judgment that any suppression and concealment by Merck was unintentional,

even though an internal memo from Merck admitted that if the truth about its process got out it could jeopardize Merck's product approvals world-wide.

In affirming, the Federal Circuit recognized that this case involves "an issue that has not been squarely addressed by this court in considering suppression or concealment as negating prior invention in a defense to an infringement suit under § 102(g) — the burdens of proof governing such a determination." The Federal Circuit, however, interpreted § 102(g) in a manner inconsistent with other sections of the patent laws and inconsistent with the Supreme Court's interpretation of *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1858); *Anderson v. Liberty Lobby*, 477 U.S. 242 (1986); and *Poller v. Columbia Broadcasting Sys.*, 368 U.S. 464 (1962). The Federal Circuit also denied Apotex's petition for panel rehearing and rehearing en banc. (Pet. App. at 46a-47a.)

REASONS FOR GRANTING THE WRIT

I. This Petition Raises A Question Of Special Importance About Multi-National Drug Companies' Participation In The Patent Systems Of Different Countries.

This case is of special importance and the Court should grant certiorari because it concerns abuse of the patent and court system of the United States and Canada by a multi-national pharmaceutical company. The operation of multi-national drug companies is a topic of major importance for global commerce and health. As can be seen on the front pages of the nation's newspapers, such multi-nationals are

centrally involved in many of the most important policy issues in the world today, from the cost of Merck's drugs for AIDS in Africa[2] to Apotex's manufacture of generic versions of Cipro to battle the threat of Anthrax as a weapon of terror.[3] The specific issue for which Apotex seeks review in ***this*** litigation is that Merck has prevailed on summary judgment on a position diametrically opposed to a position on which it prevailed before in a Canadian litigation, unjustly denying Apotex of its patent on a method of making a drug that Merck for its own benefit suppressed and concealed from the public for years. In this age of global commerce and medicine, one should not be permitted to take opposite positions in the courts of two different countries and prevail in both. For the reasons explained in this petition, Apotex respectfully requests that this Court grant certiorari to review the decision of the United States Court of Appeals for the Federal Circuit and correct the injustice effected in that court's decision.

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2. Barton Gellman, *A Turning Point That Left Millions Behind: Drug Discounts Benefit Few While Protecting Pharmaceutical Companies' Profits*, THE WASHINGTON POST, Dec. 28, 2000, at A1; Karen DeYoung, *Makers of AIDS Drugs Drop S. Africa Suit*, THE WASHINGTON POST, April 19, 2001, at A13; Jon Jeter, *Trial Opens in South Africa AIDS Drug Suit: Firms Seek to Block Law Allowing Generic Substitutes for Patented Medicines*, THE WASHINGTON POST, March 6, 2001, at A1.

3. Amy Harmon & Robert Pear, *Canada Overrides Patent for Cipro to Treat Anthrax*, THE NEW YORK TIMES, October 19, 2001 at A1; Terence Chea, *Drug Firm Plays Defense in Anthrax Scare: For Now, U.S. Declines to Suspend Bayer's Patent and Authorize Generic Cipro*, THE WASHINGTON POST, Oct. 20, 2001 at A4.

II. This Case Presents Important Questions Of Federal Law That Have Not Been, But Should Be, Decided By This Court.

A. Merck must prove that the U.S. public received the benefit of this disclosure.

The origins of the doctrine now codified in § 102(g), favoring a second inventor over a first who has abandoned, suppressed, or concealed the invention, is inherent in the Constitutional basis of the patent laws. *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1858); *accord*, *Paulik v. Rizkalla*, 760 F.2d 1270, 1273 (Fed. Cir. 1985) (en banc). In *Kendall*, this Court explained that one "who withholds his invention from the public, comes not within the policy or objects of the Constitution or acts of Congress," and therefore refused to invalidate a patent based on concealed prior invention. Permitting Merck to invalidate Apotex's patents in this way frustrates not only the Patent Act, but also the Constitutional basis for the U.S. Patents laws. Accordingly, Merck (who here has the burden of proof) must come forward with clear and convincing evidence to prove that the public ***in the United States*** has gained knowledge of the invention. *See Palmer v. Dudzik*, 481 F.2d 1377, 1387 (C.C.P.A. 1973). Merck has not met that burden. The evidence that the United States public had ***not*** gained knowledge of the invention is set forth above. At the very least there is a genuine issue of material fact on this point, which requires the reversal of summary judgment. The Constitutionally sanctioned purpose "to promote the progress of science and the useful arts" necessarily means to promote the progress of science and the useful arts ***in the United States***. All the Congressional powers listed in art. I, § 8, are of course directed towards the United States. It would entirely frustrate the Constitutional

purpose of the patent laws if one could avoid the consequences of suppression and concealment by revealing the invention only in a foreign location so remote and in such circumstance that there is no reasonable possibility that the United States public ever would receive the benefit of that disclosure.

B. Section 282 required Merck to identify the alleged inventor.

Another reason to grant this writ is to construe a federal statute, 35 U.S.C. § 282 (1994 Supp. V). The district court entered summary judgment of invalidity under 35 U.S.C. § 102(g) (2000), that some unidentified Merck employee had invented the process and that it had not been abandoned suppressed or concealed. But § 282 precludes Merck from even ***asserting*** that defense of prior inventor without first identifying the name and address of the alleged prior inventor.

Section 282 in general concerns practice and procedure in infringement litigation. In § 282, paragraph 1 provides for the presumption of validity and paragraph 2 requires that certain defenses, if asserted, must be pleaded. Paragraph 3, which is relevant here, expressly requires the defendant, Merck to provide certain information in order to even ***assert*** at trial defenses such as invalidity or prior inventorship:

> In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as

> anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and ***the name and address of any person who may be relied upon as the prior inventor*** or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires. . . .

35 U.S.C. § 282 (emphasis added). Just as Merck may not assert invalidity without identifying the relevant prior art, so here it may not assert prior inventorship without identifying the alleged prior inventor.

The Federal Circuit considered the presumption of validity under § 282, 1st paragraph, as affecting the relevant burdens of proof under § 102(g). In the context of § 102(g), however, the presumption of validity under § 282, 1st paragraph, is only ***part*** of what the statute requires. That same section also provides ***express*** disclosure requirements that must be met before even ***asserting*** this defense. Because Merck has not provided the statutorily required information, it cannot even assert this defense. This requirement is thus part of Merck's prima facie case as required by statute.

Merck, as the party asserting invalidity under § 102(g), must bear the burden of proving this defense by clear and convincing evidence. Any showing by Merck which does not provide this mandatory, preliminary identification of the name and address of the prior inventor cannot, as a matter of law, suffice as clear and convincing proof of prior inventorship negating suppression and concealment.

The grant of summary judgment must be viewed through the prism of the relevant evidentiary burden, *Anderson v. Liberty Lobby*, 477 U.S. 242, 255-56 (1986), and Merck must at least meet this condition precedent to the defense it seeks to assert.

The importance of identifying the particular alleged prior inventor was underscored by a recent amendment to § 102(g), which added the word "inventor." This amendment did not ***change*** the law, because application of § 102(g) has ***always*** depended on a specific, named inventor, identification of whom has ***always*** been required under § 282. Indeed, the requirement to identify alleged prior inventors by name and address is much, much older than the 1952 Act drafted half a century ago.

The Patent Act of 1793 provided for notice, in writing, thirty days before trial, of any special matter such as "discovery of another person." 1 STAT. 318, § 6 (Feb. 21, 1793). In 1836 Congress retained the requirement of thirty days written notice, adding that the notice must include "names and places of residence." 5 STAT. 117, § 15 (July 4, 1836). The requirement was retained in 1870, 16 STAT. 198, § 61 (July 8, 1870), from which it was codified in Rev. Stat. § 4920. Although the Federal Rules of Civil Procedure superseded that provision, Congress deemed the requirement sufficiently important that it expressly reinstated it in the 1952 act in 35 U.S.C. § 282. *See* 35 U.S.C. § 282, Revision Notes; P.J. Federico, Comments on the New Patent Act, 35 U.S.C.A. (1954), *reprinted in* 75 J.P.T.O.S. 161, 216 (1993). Many cases confirm the requirement of these various acts. *E.g.*, *Roemer v. Simon*, 95 U.S. 214, 219 (1877); *Seymore v. Osborne*, 78 U.S. (11 Wal.) 516, 539, 549 (1870); *Wise v. Allis*, 76 U.S. (9 Wal.) 737, 739–40 (1869); *Agawan Co. v.*

Jordan, 74 U.S. (7 Wal.) 583, 596 (1868); *Teese v. Huntingdon*, 64 U.S. (23 How.) 2, 10 (1859).

Here, it is undisputed that Merck never identified the name and address of the alleged prior inventor, even though it was required to provide that information. Having never provided this information, Merck may not now even assert this defense. Apotex therefore respectfully requests that the previously filed petition for rehearing be granted, that summary judgment in favor of Merck be vacated, and that the case be remanded to the trial court.

III. The Federal Circuit Has Sanctioned So Far A Departure By The District Court From The Accepted And Usual Course Of Judicial Proceedings As To Call For An Exercise Of The Court's Supervisory Powers.

The inconsistent and hypocritical positions Merck has taken in Canada and in the United States amount to a fraud on the patent system. Merck successfully suppressed and concealed this process even as it prosecuted a lawsuit in Canada to enforce its drug patent there. When Apotex discovered that process, despite Merck's suppression and concealment, Merck was then allowed to invalidate Apotex's U.S. patent, destroying its federal property right, on summary judgment. The potential cost of Merck's pharmaceutical fraud could well be billions of dollars. Only the Federal Circuit's radical departure from the usual course of judicial proceedings made possible Merck's fraud. This Court should grant certiorari and intervene to correct that error.

A. The Federal Circuit unacceptably departed from the usual course of judicial proceedings by allowing Merck to obtain summary judgment taking a position opposite to a position on which it has prevailed in an earlier litigation.

The grant of summary judgment directly conflicts with the decision of the Canadian court at *Merck & Co. Inc. v. Apotex Inc.*, [1994] 59 C.P.R. (3d) 133, *reprinted in* L10-L63. Such a conflict with a foreign court is one reason for granting certiorari. *See Aetna Ins. Co. v United Fruit Co.*, 304 U.S. 430, 960 (1938). In *Aetna*, the Court granted certiorari because a decision of a circuit court of appeals was in conflict with the decision of a Court of Queen's Bench on a question of maritime law and insurance. So, here, the decision of the district court and of the Court of Appeals for the Federal Circuit, holding that Merck did not suppress or conceal its alleged prior invention, directly conflicts with the finding of the Canadian court where Merck argued that it did not use the process covered by the patent here in suit.

Judge MacKay in the 1994 Canadian trial found that the experts there could not tell that a reaction converted enalapril maleate to enalapril sodium, the reaction that is crucial to the invention:

> The difficulty encountered is said to be that including the compound enalapril maleate, here said to be the active ingredient, in both VASOTEC and APO-ENALAPRIL, with regularly accepted adjuvants, as the patent indicates, presented a major problem in assuring stability of the product and avoiding undue disintegration. Dr. Sherman, who was directly responsible for overseeing

> product formulation at Apotex, said that in his experience the development of a product for consumption in dosage form where the active ingredient was comparatively small was a "no-brainer", easily accomplished. In this particular case, however, he had encountered the most difficulty of any product development in his experience. From document production by Merck, for counsel's eyes only by agreement, it was apparent that addition of one common adjuvant, sodium carbonate or sodium bicarbonate, was a part of Merck's tablet development and questions were asked in the course of discovery about this. Questions were also raised at trial, of Dr. Schwartz, an expert appearing for the plaintiffs, and Drs. Niebergall and McClelland, experts for the defendant. The questions sought confirmation that the Merck process of tablet formulation may well have been inventive in the manner of its resolution of the problem of disintegration, by producing a reaction through use of sodium carbonate or bicarbonate, and water, that solved the stability problem but left something other than enalapril maleate as the active ingredient. ***None of the experts could confirm this was the inevitable result of the information provided to them***, though all confirmed that ***depending upon the process of mixing and the relative volume of water mixed***, a reaction could be expected.

(L58.) Thus, in the 1994 Canadian trial Merck continued to ***deny*** that a reaction occurred, the very thing that is the claimed novelty of the patented process. Moreover, Merck ***prevailed*** in that position. Merck knew that such a reaction

occurred, and ***did not disclose that fact even to its own expert witness, Dr. Schwartz.*** Merck must now be judicially estopped to assert that it disclosed such a reaction, which is the claimed novelty of the patent in suit.

Indeed, when it suited Merck's purpose it also argued that product labels reflect final contents, not initial ingredients for a chemical reaction. In another Canadian lawsuit in 1999 against Nu-Pharm, Merck relied on the fact that Nu-Pharm's label listed enalapril maleate in its contents as proof that the product contained enalapril maleate and not enalapril sodium. Merck adduced "pictures of bottles of Nu-Enalapril tablets whose ***labels*** indicate that they contain enalapril maleate . . . [and] the ***product monographs*** of Nu-Enalapril and Apo-Enalapril . . . all stating that the Nu-Enalapril tablets contain enalapril maleate." (L72-L73.) Merck's labels and monographs should be interpreted the same way, as falsely indicating that its final product contains enalapril maleate, not enalapril sodium.

This evidence creates a genuine issue as to the underlying fact of Merck's alleged disclosure of its process and whether, instead, Merck intentionally suppressed and concealed its process, thus precluding summary judgment. The Federal Circuit's grant of summary judgment should be reviewed by writ of certiorari.

B. The Federal Circuit unacceptably departed from the usual course of judicial proceedings by ignoring evidence of intentional suppression and concealment creating a genuine issue of material fact.

Patent law distinguishes between two types of suppression or concealment: one in which an inventor ***intentionally*** suppresses or conceals his invention, and another involving a ***legal inference*** of suppression or concealment based on unreasonable delay. *Paulik v. Rizkalla*, 760 F.2d 1270, 1273 (Fed. Cir. 1985). The district court and court of appeals both assumed that this case was about concealment inferred from delay, but Apotex identified evidence of record showing ***intentional*** concealment.

The record on summary judgment is considered in the light most favorable to Apotex, the party opposing the motion. *Poller v. Columbia Broadcasting Sys.*, 368 U.S. 464, 473 (1962). Here, Merck's summary judgment should not have been granted. Summary procedures should be used sparingly in complex litigation where motive and intent play leading roles, the proof is largely in the hands of the alleged tortfeasors, and hostile witnesses thicken the plot. *Id.* In *Poller* this Court considered an antitrust case, but patent litigation is no less complex. Proof of Merck's intentional concealment, like proof of the conspiracy in *Poller*, is largely in the hands of the party that here received summary judgment. As the Court in *Poller* noted:

> It is only when the witnesses are present and subject to cross-examination that their credibility and the weight to be given their testimony can be appraised. Trial by affidavit is no substitute for

> trial by jury which so long has been the hallmark of "even handed justice."

Poller, 368 U.S. at 473 (1962).

The record indicates that Merck misled the public to protect its financial interest in VASOTEC. To designedly withhold an invention from the public for one's own benefit is to suppress it. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1567 (Fed. Cir. 1996).

In an internal document, Merck admitted:

> [W]e have a major concern regarding the presence of a statement on the product label which infers the formation of a sodium salt of enalapril maleate. ***Such a statement might affect worldwide registration of the product and existing approved labeling.***

(L108) (emphasis added). This statement reveals Merck's motive to suppress and conceal the reaction that forms "a sodium salt of enalapril maleate", i.e., enalapril sodium. ***That very reaction is crucial to the invention.*** Given this evidence of motive, the inference of intent reasonably could (and on summary judgment was required to be) drawn in Apotex's favor.

Some commentators on patent law suggest that such ***intentional*** suppression and concealment in patent law ***cannot*** be cured. *See* Robert L. Harmon, PATENTS AND THE FEDERAL CIRCUIT 108–109 (4th ed. 1998) ("[D]eliberate suppression or concealment of an invention . . . ***is probably not curable by resumption of work***. . . .") (emphasis added).

Even if Merck can negate its deliberate suppression and concealment, it must prove clearly and convincingly that the public has gained knowledge of the invention to insure its preservation in the public domain. *Palmer*, 481 F.2d at 1387 ("[T]he question . . . ought to be determined by asking whether the public has gained ***knowledge of the invention*** which will ***insure its preservation*** in the public domain.") (emphasis added). One who keeps knowledge of the invention from the public suppresses that invention. *Young v. Dworkin*, 489 F.2d 1277, 1279 (C.C.P.A. 1974).

Apotex offered evidence that a mock-up video Merck used in the 1994 Canadian trial suppressed the patented process by concealing a chemical reaction that converted enalapril maleate to enalapril sodium without forming a clear solution in water. McLeod, who narrated the video, admitted it was "not really enalapril or the ingredients." He admitted that Merck "chose not to use the active ingredients," even though "there was no reason not to."

Dr. Sherman's declaration notes that McLeod admitted that the process required "a specified amount of water," but that he never specified the amount Merck used. (L104.) Dr. Schwartz, Merck's expert in the 1994 Canadian suit, admitted that he could not tell whether the required reaction occurred. He knew one would get a reaction with everything in ***solution*** but that is shown in the prior art as disclosed in the patents in suit. Dr. Schwartz also admitted that any reaction would depend on the ***amount*** of water involved and the ***order*** of the mixture, which the video concealed. He identified several possible roles for sodium bicarbonate, thus confirming that the presence of sodium bicarbonate does not reveal the patented process. Similarly, Apotex's experts in Canada, Drs. Niebergall and McClelland, could not be sure

that a reaction occurred because no information was given about whether there was enough water. (L58.)

Dr. Scheindlin and Dr. Sherman both attest that the video conceals: (1) the use of sodium bicarbonate; (2) any chemical reaction between the sodium bicarbonate and enalapril maleate; and (3) that a chemical reaction produces, inter alia, enalapril sodium. (L104-L106.) Merck has conceded that McLeod admitted he never identified sodium bicarbonate, but merely mentioned the presence of an unnamed stabilizer. Dr. Scheindlin specifically stated, "Mr. McLeod's use of the word 'stabilizer' in his 1994 testimony ***is deceptive.*** Sodium bicarbonate does not act as a stabilizer per se, but rather is an important ingredient of a chemical reaction to convert enalapril maleate to enalapril sodium." (L106) (emphasis added). Dr. Sherman confirmed that the implication that VASOTEC contained enalapril maleate plus an unidentified ***stabilizer***, was ***untrue***. (L104.)

The testimony of Merck's expert Dr. Schwartz in the 1994 Canadian trial, that no reaction could be shown to have occurred, is analogous to the testimony of the prior inventor's technical director in *Palmer*, 481 F.2d at 1384–85. Just like the testimony in *Palmer*, the prior testimony of Dr. Schwartz "indicates that the invention was not necessarily apparent even to one skilled in the art." *Id.* In *Palmer*, the C.C.P.A. noted that this fact "supports the legal conclusion of the board that Palmer concealed the invention within the meaning of § 102(g)." So, here, the ***fact*** that Dr. Schwartz did not appreciate that a reaction occurred is ***material*** to the legal conclusion of suppression and concealment.

C. The record as a whole does not clearly and convincingly show the absence of a genuine issue of fact.

In its new drug application ("NDA") on VASOTEC, its product labeling, the 1988 *Dictionnairre Vidal*, and the Product Monograph, Merck stated that the contents of the ***final tablet*** that would be sold would include enalapril maleate and sodium bicarbonate, when in truth the final contents are enalapril sodium and byproducts of a enalapril maleate/sodium bicarbonate reaction. By listing starting ingredients ***as though they were final contents***, Merck intentionally suppressed and concealed the reaction crucial to the patented process. Merck conceded that VASOTEC tablets contain enalapril sodium and ***not*** enalapril maleate, and that it ***never*** publicly disclosed, (in the *Dictionnairre Vidal*, the Product Monograph, or elsewhere), that VASOTEC tablets contain enalapril sodium or that the enalapril maleate is reacted in the tableting process.

There is no *evidence* in the record that anyone would interpret Merck's descriptions as the starting ingredients for a manufacturing process. All the ***evidence*** supports Apotex. Dr. Scheindlin (L86-L89, L105-L107), Dr. Carstensen (L82-L85), and Dr. Sherman (L90-L104), explained that anyone reading the product monograph could have only one understanding — that each tablet in the bottle, in the physician's hand, and in the patient's mouth contained the active ingredient enalapril maleate, not enalapril sodium, and inactive ingredients including sodium bicarbonate.

Dr. Scheindlin also identified false and misleading statements in Merck's NDA that suppressed and concealed

the process. Merck was supposed to disclose the contents of the final VASOTEC tablets in subsection 7 of its 1983 NDA for VASOTEC tablets. Instead it repeated the initial ingredients from subsection 6. Merck conceded that it there concealed that VASOTEC tablets contained enalapril sodium, disodium maleate, and monosodium maleate. In subsection 8, where Merck was supposed to identify the details in its manufacturing process, it never explained that a reaction occurred to convert enalapril maleate to enalapril sodium.

Apotex's inability to reverse engineer the process in 1990 (before Dr. Sherman's invention) is additional evidence of Merck's effective suppression and concealment. Apotex used the description of contents in the physician's desk reference plus its analysis that suggested the presence of sodium bicarbonate. Apotex found that stability actually ***decreased*** when it mixed these two components without using the patented process. Thus, listing of enalapril maleate (and ***not*** enalapril sodium) as the contents of VASOTEC effectively concealed and suppressed the process even when Apotex tried to reverse engineer it.

Whenever § 102(g) is an issue in litigation, there is always at least one person who uncovered the invention despite any concealment and suppression — the subsequent inventor. Because of the statutory presumption of validity, and in the absence of derivation, that person's inventive insight cannot itself be clear and convincing evidence on summary judgment to negate suppression and concealment. Here, the only proof offered of the ***sufficiency*** of Merck's disclosures to negate suppression and concealment is that Dr. Sherman admitted: (1) that the final enalapril sodium product in the VASOTEC® tablets was the result of an acid-base chemical reaction between enalapril maleate and sodium

bicarbonate in water; and (2) that his inspection of the VASOTEC® tablets that Merck sold commercially revealed that they were made using a wet granulation process. (Pet. App. at 16a-17a.) This evidence is insufficient.

Dr. Sherman's supposed admissions were, in fact, the insights of another inventor who had been studying the problem since 1990. Indeed, his "Statement of Facts" containing the alleged admissions was made in the three-week interval between his conception and reduction to practice. At this juncture it must be presumed (drawing all inferences in Apotex's favor) that Dr. Sherman ***did not*** derive his invention, because the district court found in another motion not appealed that this issue was genuinely disputed. Moreover, the Patent Office concluded that the process Dr. Sherman invented and claimed was patentable over the prior art, including Merck's patent on enalapril maleate and other patents on other processes for making it. Dr. Sherman's invention is therefore not evidence negating suppression and concealment, because the non-derived invention of another inventor in Canada is not probative of whether the United States ***public*** has gained knowledge of the invention that will insure its preservation in the public domain.

On the contrary, all the evidence about what the ***United States public*** might have known shows that Merck's intentional suppression was effective. The 1994 Canadian trial included the product monograph and the testimony of McLeod that Merck relies on as its disclosures. Expert witnesses there, however, could not say whether Merck used the now patented process. Even Merck's own expert witness Dr. Schwartz, the only member of the United States public there present, did not know. If Dr. Schwartz (who knows more about this field than the general United States public)

did not know of this reaction, that is substantial evidence that the process was still effectively suppressed and concealed. MacKay, J., in the passage quoted above, described the suggested process as "inventive" and concluded that he could not find, on evidence including the monograph and McLeod's testimony, that any such reaction occurred. MacKay, J., in effect, concluded the opposite of the supposed admissions in the Statement of Facts.

The grant of summary judgment premised on a contrary finding should be reviewed by writ of certiorari. Even if Dr. Sherman's supposed admissions were probative, which they are not, they still would not be dispositive. Even if it was known to use a wet granulation process, such a process may be performed using not only water but also alcohol — the product monograph indicated that enalapril maleate is more soluble in the latter. And even if it were known to use water to permit a reaction, one still would not know from looking at the tablet to use the patented process instead of the known prior art process, which produced that result. Although it is possible to analyze VASOTEC tablets to determine that they contain sodium, it is not possible to reverse engineer the process by which they are made and, in particular, it is not possible to discern by reverse engineering that they do not use the known prior art process.

CONCLUSION

For the reasons set forth above, Apotex respectfully requests that certiorari to the United States Court of Appeals for the Federal Circuit be granted for the purpose of reviewing its grant of summary judgment in this litigation.

Respectfully submitted,

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